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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/499,006	02/04/2000	Dr. Paddy Jim Baggot	249/127	9604

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EXAMINER	
JOHANNSEN, DIANA B	
ART UNIT	**PAPER NUMBER**
1634	

DATE MAILED: 10/07/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/499,006	BAGGOT, DR. PADDY JIM	
	Examiner	Art Unit	
	Diana B. Johannsen	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *01 August 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 15-24* is/are pending in the application.

4a) Of the above claim(s) *1 and 17* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *15-16 and 18-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

FINAL REJECTION

1. This action is in response to the Amendment and Response filed February 21, 2003. Claims 15 and 21 have been amended, and claims 15-16 and 18-24 are now under consideration. The amendments and arguments have been thoroughly reviewed, but are not persuasive for the reasons that follow. Any rejections not reiterated in this action have been withdrawn as being obviated by the amendment of the claims. **This action is FINAL.**

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claim Rejections - 35 USC § 112

3. Claims 15-16 and 18-24 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, for the reasons set forth in the Office action of October 21, 2002.

The response traverses the rejection on the following grounds. The response refers to pages 4-5 of the specification, and argues that "the body fluid that is the source of" the data at pages 7-16 and "the method used to produce it, are clearly set forth in the specification." The response further refers to page 7 of the specification, where under the heading "Example Profile Analysis" it is stated that "Using the aforementioned GC/MS procedure, a metabolic profile for a group of 23 Down Syndrome patients was generated." Applicant urges that "it is beyond dispute that the specification discloses

amniotic fluid as the body fluid employed to produce the data provided in the specification, expressly discloses the data allowing one to diagnose and identify Down Syndrome in a fetus by levels of metabolites in amniotic fluid, and expressly discloses the method in which differences in the quantities of a plurality of metabolites in amniotic fluid are employed in the diagnosis of Down Syndrome."

These arguments have been thoroughly considered but are not persuasive for the following reasons. First, it is acknowledged that the specification states at, e.g., pages 4-5 that Applicant's method of diagnosing chromosomal abnormalities is to be performed on amniotic fluid "taken from around the fetus during pregnancy." However, at page 7 of the specification, prior to the recitation of Applicant's data, the specification states "To diagnose a fetus for chromosomal abnormalities using the method of the present invention, a metabolic profile must first be generated that is representative of the metabolite levels in an average patient suffering from the chromosomal abnormality that is to be diagnosed." Accordingly, Applicant's example is not in fact an exemplification of the diagnosis of chromosomal abnormalities in a fetus, but rather, a disclosure of the generation of profiles for use in the method. The example refers to profiles generated that are "representative of the metabolite levels in an average patient," and further reports results obtained from "a group of 23 Down Syndrome patients" and "a group of 41 normal patients." No reference is made throughout the example either to amniotic fluid or to, e.g., a sample obtained from around a "fetal patient." Further, in describing the use of amniotic fluid at pages 4-5, the specification refers to amniotic fluid obtained from around a fetus, but never uses the terminology

"patient" to refer to a fetus, and the specification never indicates that the term "patient" is, e.g., used in the context of the specification to refer to a fetus. Accordingly, absent some kind of definition or other indication in the specification that the term "patient" may refer to a fetus, and/or an actual disclosure in the Example of the origin of the samples examined, one of skill in the art would give the term "patient" its usual meaning, and it would appear to one of skill that the data presented by Applicant was obtained by examining normal patients and Down Syndrome patients, as is actually stated in the example. It is again noted that the Example is not disclosed as being an exemplification of the claimed method, but rather as being the generation of profiles "representative of the metabolite levels in an average patient," as stated at page 7. Thus, the specification does not actual provide evidence that one may diagnose or identify Down Syndrome in a fetus by comparing levels of metabolites in amniotic fluid. Further, Applicant has not provided any kind of declaratory evidence that, e.g., the data provided in the specification was actually obtained using amniotic fluid obtained from, e.g., a population of pregnant women whose babies were found to have Down Syndrome (and a control group of women carrying healthy babies), as opposed to a population of "Down Syndrome patients" and a population of "normal patients," as stated in the specification. Accordingly, Applicant's arguments are not persuasive, and this rejection is maintained.

THE FOLLOWING ARE NEW GROUNDS OF REJECTION NECESSITATED BY APPLICANTS AMENDMENTS TO THE CLAIMS:

4. Claims 15-16 and 18-24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 15-16, 18-20 and 24 are indefinite over the recitation of the phrase "comparing the patient profile with a control profile representative of normal levels of each metabolite, wherein the control profile lists a quantity for each respective metabolite of the patient profile that is present in amniotic fluid or persons with Down Syndrome" in claim 15. First, it is unclear whether the recitation "amniotic fluid of persons with Down Syndrome" is intended to refer to amniotic fluid present in a pregnant Down Syndrome patient, or to amniotic fluid surrounding a fetus with Down Syndrome (and thus it is further unclear as to the type of control profile employed in the method of the claims). Second, it is unclear from this recitation as to whether the claims require a control profile "representative of normal levels" or a control profile "present in amniotic fluid of persons with Down Syndrome" (or both). The claims as amended do not make clear what type of control profile or profiles are employed in the method (and further, how they are employed).

Claims 15-16, 18-20 and 24 are indefinite over the recitation of the phrase "a quantity of a subset of metabolites" in claim 15. It is unclear as to whether this recitation is intended to actual refer to differing quantities for a subset of metabolites, or whether this recitation requires a single quantity (e.g., a sum of the quantities of "a subset of metabolites"). Clarification is required.

Claims 21-24 are indefinite over the recitation of the phrase "amniotic fluid of a patient known to have Down Syndrome" in claim 21. It is unclear whether this recitation is intended to refer to amniotic fluid present in a pregnant Down Syndrome patient, or to amniotic fluid surrounding a fetus with Down Syndrome.

Conclusion

5. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diana B. Johannsen whose telephone number is 703/305-0761. The examiner can normally be reached on Monday-Friday, 7:30 am-4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached on 703/308-1152. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703/308-0196.

Diana B. Johannsen
October 6, 2003

CARLA J. MYERS
PRIMARY EXAMINER